AMENDED IN ASSEMBLY APRIL 7, 2005

AMENDED IN ASSEMBLY FEBRUARY 11, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 71

Introduced by Assembly Members Chan and Frommer (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, and Pavley)

January 3, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 71, as amended, Chan. Pharmaceuticals: adverse drug reactions: Office of California Drug Safety Watch.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would establish the Office of California Drug Safety Watch within the department and would require the office ~~to establish a toll-free telephone number for the purpose of receiving reports of adverse drug reactions, establish a Web site to provide up-to-date information to the public about adverse drug reactions, maintain a database of adverse drug reaction reports, and act as a liaison with all appropriate parties to ensure the speedy and accurate flow of information about important drug safety issues~~*, among other duties, to establish a central repository of information about the safety and effectiveness of prescription drugs, to disseminate information to*

health care professionals and consumers through an Internet Web site, to request assistance from the University of California and California State University, and to rely on systematically reviewed evidence-based research.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Since 1997, when the United States Food and Drug Administration (FDA) allowed drug manufacturers to advertise directly to consumers, the amount spent on advertising has risen dramatically.

(b) According to the United States General Accounting Office (GAO) report, the pharmaceutical industry spent $2.7 billion in 2001 on direct-to-consumer advertising. A December 6, 2004, New York Times report states that such spending has reached $3.8 billion.

(c) According to the same GAO report, while overall spending on drug promotion was less than spending on research and development ($19.1 billion versus $30.3 billion), spending on direct-to-consumer advertising is increasing at a faster rate than overall drug promotion spending or spending on research and development. Between 1997 and 2001, the increase in direct-to-consumer advertising was 145 percent compared to a 59 percent increase for research and development.

(d) Although the FDA is responsible for postmarket surveillance of prescription drugs, numerous concerns have been raised about the adequacy of these efforts.

(e) An unpublished internal FDA study from 2002 revealed that 18 percent of FDA scientists reported being pressured to approve a new drug "despite reservations about the safety, efficacy or quality of the drug."

(f) A 1999 FDA survey and a Kaiser Family Foundation survey both found that more than 50 million people respond to drug advertisements by asking their doctor whether the advertised medications might work for them. At the same time,

both surveys showed that almost 60 percent of consumers found the side-effect warnings in these advertisements to be inadequate.

(g) Pressure to get new drugs to market, combined with the vast amount of drug marketing undertaken by manufacturers, make it difficult to address a threat once it is identified. Recent studies linking the use of popular, widely promoted prescription drugs to serious public health concerns point to the need for greater oversight to protect the public.

(h) Californians do not have a reliable central repository of information about prescription drug safety and effectiveness.

(i) California physicians and other prescribers could benefit from a reliable central repository of information about prescription drug safety and effectiveness.

(j) The Oregon Drug Effectiveness Review Project is developing information that could be used for a central repository of information about prescription drug safety and effectiveness. The State Department of Health Services, CalPERS, and the California Healthcare Foundation all participate in the Oregon Drug Effectiveness Review Project.

(k) Safer and more effective prescription drugs within a class may also be among the less expensive prescription drugs within that class, meaning that a reliable central repository of information about prescription drug safety and effectiveness would create opportunities for prescription drug cost savings.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Office of California Drug Safety Watch

111657. *(a)* There is hereby established in the State Department of Health Services the Office of California Drug Safety Watch, which shall do all of the following*, to provide Californians with information on the safety and effectiveness of prescription drugs*:

~~(a) Establish a toll-free telephone number for the purpose of receiving reports of adverse drug reactions.~~

~~(b) Establish a Web site to provide up-to-date information to the public about adverse drug reactions.~~

~~(c) Maintain a database of adverse drug reaction reports.~~

~~(d) Act as a liaison with all appropriate parties, including the United States Food and Drug Administration, drug manufacturers, pharmacists, physicians, health care providers, and consumer drug safety organizations, to ensure the speedy and accurate flow of information about important drug safety issues.~~

(1) Establish a central repository of information about the safety and effectiveness of prescription drugs.

(2) Disseminate information to California health care professionals and consumers through an Internet Web site that shall include links to other relevant Web-based information that has been professionally reviewed and approved.

(3) Ensure that the dissemination of information is done in a culturally competent manner.

(4) In selecting therapeutic classes of drugs about which to develop information, give priority to therapeutic classes that have one or all of the following characteristics:

(A) Classes of drugs for which there have been recently published reports of safety concerns.

(B) Classes of drugs that have been advertised on television directly to consumers.

(C) Classes of drugs for which there is recently published systematically reviewed evidence-based research.

(5) Request appropriate units of the University of California and the California State University to provide assistance.

(6) Rely on systematically reviewed evidence-based research.

(b) The office shall have the authority to review the formularies of all state-funded programs for their use of systematically reviewed evidence-based research.

(c) The office shall coordinate its activities with other state departments and agencies to avoid unnecessary duplication.

111657.1. For purposes of this article, the following terms have the following meanings:

(a) "Evidence-based research" means prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups.

(b) "Systematically reviewed" means review of evidence-based research that uses rigorous, unbiased methods to examine the similarities and differences of results across many individual research studies. The goal of a systematic review is to

estimate the comparative effectiveness and safety of health care treatments. A systematic approach to reviewing the evidence increases the reliability of the results, and the transparency of the procedures.

O